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**INFORMATION  
DISCLOSURE STATEMENT**

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Attorney Docket	UCSF-088CON2
First Named Inventor	STERN, ROBERT
Application Number	To Be Assigned
Confirmation No.	To Be Assigned
Filing Date	July 18, 2003
Group Art Unit	To Be Assigned
Examiner Name	To Be Assigned
Title:	"HUMAN PLASMA HYALURONIDASE"

Sir:

This is an Information Disclosure Statement submitted for the Examiner's consideration. A Form PTO-SB/08A listing the references and copies of the cited references accompany this paper. Applicants would appreciate the Examiner's initialing and returning the form to indicate that the references have been reviewed and made of record.

**All of the references identified herein were disclosed in parent application serial number 09/795,914, filed 2/27/2001 and as such, copies thereof are not included pursuant to the provisions of 37 CFR § 1.98(d).**

This Information Disclosure Statement is not intended as a representation that a search has been made, that additional information material to the examination of this application does not exist, or that any one of the above references constitutes prior art to the present application within the meaning of 35 U.S.C. § 102.

As applicants have not yet received a first Action on the merits, no fee is believed to be required for filing this Disclosure Statement. If, however, the PTO finds that for some reason a fee is due, our Deposit Account No. 50-0815, Order No. UCSF-088CON2 may be charged thereon.

Respectfully submitted,  
BOZICEVIC, FIELD & FRANCIS LLP

Date: July 18, 2003

By: 

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<b>INFORMATION DISCLOSURE CITATION</b> <b>Form PTO-1449 (Modified)</b> <i>(Use several sheets if necessary)</i>	<b>ATTY. DOCKET NO.</b> UCSF088CON	<b>SERIAL NO.</b> 09/795,914
	<b>APPLICANT</b> Stern et al.	
	<b>FILING DATE</b> February 27, 2001	<b>GROUP</b> 1642

### U.S. PATENT DOCUMENTS

Examiner Initial	Document Number	Date	Name	Class	Subclass	Filing Date If Appropriate
AA	3,945,889	03/23/1976	Mima et al.			
AB	5,427,779	06/27/1995	Elsner et al.			

### FOREIGN PATENT DOCUMENTS

	Document Number	Date	Country	Class	Subclass	Translation	
AC	WO 88/02261	04/07/88	PCT			Yes	No
AD	WO 89/05329	06/15/89	PCT				
AE	WO 96/03497	02/08/96	PCT				

### OTHER ART (Including Author, Title, Date, Pertinent Pages, Etc.)

AF	Afify et al., (1993) "Purification and Characterization of Human Serum Hyaluronidase" Arch. Biochem. Biophys. 305 (2):434-441.						
AG	Baumgartner et al., (1988) "Phase I Study in Chemoresistant Loco-regional Malignant Disease with Hyaluronidase" Reg. Cancer Treat. 1:55-58.						
AH	Beckenlehner et al., (1992) "Hyaluronidase Enhances the Activity of Adriamycin in Breast Cancer Models in Vitro and in Vivo" J. Cancer Res. Oncol. 118:591-596.						
AI	Bonner et al., (1966) "Colorimetric Method for Determination of Serum Hyaluronidase Activity" Clinica Chimica Acta 13:746-752.						
AJ	Bordier, (1981) "Phase Separation of Integral Membrane Proteins in Triton X-114 Solution" J. Biol. Chem. 256(4):1604-1607.						
AK	Cashman et al., (1969) "The Hyaluronidase of Rat Skin" Arch. Biochem. Biophys. 135:387-395.						
AL	Czejka et al., (1990) "Influence of hyaluronidase on the blood plasma levels of 5-fluorouracil in patients," Pharmazie 45:H.9.						
AM	De Maeyer et al., (1992) "The Growth Rate of Two Transplantable Murine Tumors, 3LL Lung Carcinoma and B16F10 Melanoma, Is Influenced by Hyal-1, A Locus Determining Hyaluronidase Levels and Polymorphism" Int. J. Cancer 51:657-660.						
AN	De Salegui et al., (1967) "A Comparison of Serum and Testicular Hyaluronidase" Arch. Biochem. Biophys. 121:548-554.						
AO	Delpech et al., (1987) "An Indirect Enzymeimmunoassay for Hyaluronidase" J. Immunol. Methods 104:223-229.						
AP	Doctor et al., (1983) "Isolation and Properties of a New Anticoagulant Protein from Commercial Bovine Testicular Hyaluronidase" Thrombosis Res. 30:565-571.						

<b>EXAMINER</b>	<b>DATE CONSIDERED</b>
<b>EXAMINER:</b> Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.	

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		<b>APPLICANT</b> Stern et al.	
		<b>FILING DATE</b> February 27, 2001	<b>GROUP</b> 1642
AQ	Dorfman et al., (1948) "A Turbidimetric Method for the Assay of Hyaluronidase" J. Biol. Chem. 172:367-375.		
AR	Fenger et al (1982) "Purification of Human Serum Hyaluronidase Using Chromatofocusing." (J. Chromatogr. 240:173-179)		
AS	Fischer-Szafarz et al., (1989) "Hyal-1, a Locus Determining Serum Hyaluronidase Polymorphism, in Chromosome 9 in Mice" Somat. Cell. Mol. Genet. 15:79-83.		
AT	Fischer-Szafarz et al., (1995) "Hyaluronidase in Human Somatic Tissues and Urine: Polymorphism and the Activity in Diseases," Acta Biochim Pol. 42:31-3.		
AU	Gabizon (1995) "Stealth Liposomes and Cancer Targeting: A Realistic Compromise in Drug Delivery." (J. Liposome Res., 5:704-710)		
AV	GenBank accession No. U03056, deposited Nov. 1, 1993.		
AW	Gregoriadis et al. (1993) "Liposomes in drug delivery. Clinical, diagnostic and ophthalmic potential." (Drugs, 45:15-28)		
AX	Guntenhoner et al., (1992) "A Substrate-Gel Assay for Hyaluronidase Activity" Matrix 12:388-396.		
AY	Harrison et al., (1988) "Multiple Forms of Ram and Bull Sperm Hyaluronidase Revealed by Using Monoclonal Antibodies" J. Reprod Fertil. 82:777-785.		
AZ	Hegi et al., (1994) "Allelotyping Analysis of Mouse lung Carcinomas Reveals Frequent Allelic Losses on Chromosome 4 and an Association between Allelic Imbalances on Chromosome 6 and K-ras Activation," Cancer Research 54, pp. 6257-6264.		
BA	Horn et al., (1985) "Intravesical Chemotherapy of Superficial Bladder Tumors in a Controlled Trial with Cis-Platinum Versus Cis-Platinum Plus Hyaluronidase" J. Surg. Oncol. 28:304-307.		
BB	Johnstone et al. (1987) (Immunocytochemistry in Practice, Blackwell Scientific Publications, Oxford, pp. 30-31)		
BC	Kimata et al., (1983) "Increased Synthesis of Hyaluronic Acid by Mouse Mammary Carcinoma Cell Variants with High Metastatic Potential" Cancer Res. 43:1347-1354.		
BD	Kohn et al., (1994) "Effects of Hyaluronidase on Doxorubicin Penetration into Squamous Carcinoma Multicellular Tumor Spheroids and Its Cell Lethality" J. Cancer Res. Clin. Oncol. 120:293-297.		
BE	Kolarova et al., (1970) "Host-Tumour Relationship XXIX. Hyaluronidase Activity and Seromucoid Concentration in Blood Serum of Patients with Cancer" Neoplasma 17:641-648.		
BF	Komender et al., (1973) "Isolation of Hyaluronidase from Kidney Extract," Bull Acad. Pol. Sci. (Biol.) 21:637-41.		
BG	Kreil, (1995) "Hyaluronidases--A Group of Neglected Enzymes" Protein Sci. 4:1666-1669.		
BH	Levy et al., (1966) "Mammalian Glycosidases and Their Inhibition by Aldonolactones" Method Enzymol. 8:571-584.		
BI	Lien et al., (1990) "Collagen, Proteoglycan and Hyaluronidase Activity in Cultures from Normal and Scoliotic Chicken Fibroblasts" Biochim. Biophys. Acta. 1034:318-325.		
BJ	Liu et al., (1996) "Expression of Hyaluronidase by Tumor Cells Induces Angiogenesis In Vivo" Proc. Natl. Acad. Sci. USA 93 (15):7832-7837.		
BK	Margolis et al., (1972) "The Hyaluronidase of Brain," J. Neurochem. 19:2325-32.		
BL	Natowicz et al., (1996) "Clinical and Biochemical Manifestations of Hyaluronidase Deficiency" N. Engl. J. Med. 335 (14):1029-1033.		

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		<b>APPLICANT</b> Stern et al.	
		<b>FILING DATE</b> February 27, 2001	<b>GROUP</b> 1642
	BM	Natowicz, et al., (1996) "Human Serum Hyaluronidase: Characterization of a Clinical Assay," Clinical. Chimica. Acta., 245:1-6	
	BN	Northrup et al., (1973) "Development of the Hyaluronidase Activity Assay As A Cancer Screening Test" Clin. Biochem. 6:220-228.	
	BO	Palowski et al., (1981) "The Effects of Hyaluronidase Upon Tumor Formation in BALB/c Mice Irradiated with Ultraviolet Light" Carcinogenesis (Proceedings of the 17th Annual Meeting of the American Society of Clinical Oncology), Washington, D.C., 22:105, (abstract 415).	
	BP	Pawlowski et al., (1979) "Effects of Hyalurodinase Upon Tumor Formation in BALB c Mice Painted with 7,12-Dimethylbenz-( $\alpha$ )Anthracene" Int. J. Cancer 23:105-109.	
	BQ	Reissig et al., (1955) "A Modified Colorimetric Method for the Estimation of N-Acetyl amino Sugars" J. Biol. Chem. 217:959-966.	
	BR	Ruggiero et al., (1987) "Hyaluronidase Activity of Rabbit Skin Wound Granulation Tissue Fibroblasts" J. Dent. Res. 66(7):1283-1287.	
	BS	Scheithauer et al., (1988) "In Vitro Evaluation of the Anticancer Drug Modulatory Effect of Hyaluronidase in Human Gastrointestinal Cell Lines" Anticancer Res. 8:391-396.	
	BT	Schuller et al., (1991) "Pharmacokinetics of Intrahepatic 5-Fluorouracil $\pm$ Preinjected Hyaluronidase (Neopermease, N)" Proc. Amer. Assoc. Cancer Res. 32:173, (Abstract No. 1034).	
	BU	Stern et al., (1992) "An Elisa-Like Assay for Hyaluronidase and Hyaluronidase Inhibitors" Matrix 12:397-403.	
	BV	Thet et al., (1983) "Changes in Lung Hyaluronidase Activity Associated with Lung Growth, Injury and Repair" Biochem. Biophys. Res. Commun. 117:71-77.	
	BW	Underhill, (1991) "CD44: The Hyaluronan Receptor" J. Cell Science 103:293-298.	
	BX	van den Berg et al., (1995) "Exogenous Glycosyl Phosphatidylinositol-anchored CD59 Associates with Kinases in Membrane Clusters on U937 Cells and Becomes Ca <sup>2+</sup> -signaling Competent" J. Cell Biology 131(3):669-677.	
	BY	Wolf et al., (1982) "The Serum Kinetics of Bovine Testicular Hyaluronidase in Dogs, Rats and Humans" J. Pharmacol. Exper. Therap. 222(2):331-337.	
	BZ	Zanker et al., (1986) "Induction of Response in Previous Chemotherapy Resistant Patients by Hyaluronidase" Proc. Amer. Assoc. Cancer Res. 27:390 (Abstract 1550).	

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PTO/SB/08A (08-00)

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Substitute for form 1449A/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  <i>(use as many sheets as necessary)</i>				<b>Complete if Known</b>	
				Application Number	09/795,914
				Filing Date	February 27, 2001
				First Named Inventor	STERN, ROBERT
				Group Art Unit	1632
				Examiner Name	CHEN, LIPING
Sheet	1	of	1	Attorney Docket Number	UCSF-088CON

U.S. PATENT DOCUMENTS						
Examiner Initials <sup>1</sup>	Cite No. <sup>1</sup>	U.S. Patent Documents		Name of Patentee or Applicant of Cited Documents	Date of Publication of Cited Document MM-DD-YYYY	Pages, columns, lines, Where Relevant Passages or Relevant Figures Appear
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FOREIGN PATENT DOCUMENTS								
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		Office <sup>3</sup>	Number <sup>4</sup>	Kind Code <sup>5</sup> (if known)				
		WO	96/31596	A1	Stern <i>et al.</i>	10-10-1996		

OTHER PRIOR ART—NON PATENT LITERATURE DOCUMENTS			
Examiner Initials <sup>1</sup>	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>

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<sup>1</sup>Unique citation designation number. <sup>2</sup>See attached Kinds of U.S. Patent Documents. <sup>3</sup>Enter Office that issued the document, by the two-letter code (WIPO Standard St.3). <sup>4</sup>For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document.

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<b>Notice of References Cited</b>	Application/Control No. 09/795,914	Applicant(s)/Patent Under Reexamination STERN ET AL.	
	Examiner Liping Chen	Art Unit 1632	Page 1 of 3

**U.S. PATENT DOCUMENTS**

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	T					

**NON-PATENT DOCUMENTS**

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	Verma, I. M. et al. "Gene Therapy- promises, Problems and Prospects" (1997) Nature Vol. 389, pp. 239-242.
	V	Orkin, S. H. et al. "Report and Recommendations of The Panel to Assess The NIH Investment in Research on Gene Therapy" (1995)
	W	Eck, S. L. et al "Gene-Based therapy" in The Pharmacological Basis of therapeutics, Goodman & Gilman's, McGraq-Hill, Ninth Edition, pp. 77-101, 1996.
	X	Rozenberg, Y. et al. "Alternative Gene Delivery" S.T.P. Pharma Sci (2001) Vol. 11, pp. 21-30.

\*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)  
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

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**NON-PATENT DOCUMENTS**

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	U	Nishikawa, M. et al. "Nonviral Vectors in The New Millennium: Delivery Barrier in Gene Transfer" (2001) Hum Gene Ther Vol. 12, pp. 861-870.
	V	Balicki, D. et al. "Gene Therapy of Human Disease" (2002) Medicine Vol. 81, pp. 69-86.
	W	Csoka, T. B. et al. "Hyaluronidases in Tissue Invasion" (1997) Invasion and Metastasis Vol. 17, No. 6, pp. 297-311.
	X	Chang N. S. "Transforming Growth Factor-beta Protection of Cancer Cells Against Tumor Necrosis Factor Cytotoxicity is counteracted by Hyaluronidase" (1998) Int J Mol Med Vol. 2, No. 6, pp. 653-659.

\*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)  
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**NON-PATENT DOCUMENTS**

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	Lepperdinger, G. et al. "Hyal2 - Less Active, But Nore Versatile?" (2001) Matrix Biol Vol. 20, pp. 509-514.
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Application/Control No.

09/795,914

Applicant(s)/Patent Under

Reexamination

STERN ET AL.

Examiner

Quang Nguyen, Ph.D.

Art Unit

1636

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**NON-PATENT DOCUMENTS**

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	Lin Ji et al. Expression of several genes in the human chromosome 3p21.3 homozygous deletion region by an adenovirus vector results in tumor suppressor activities in Vitro and in Vivo. Cancer Res. 62:2715-2720, 2002.
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